

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

JOSEPH W. DYKSTRA,

Plaintiff,

v.

WYETH PHARMACEUTICALS, INC.,

Defendant.

Case No. 08-CIV-7432(CS)(GAY)

**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT WYETH
PHARMACEUTICAL INC.'S MOTION TO DISMISS**

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Attorneys for Defendant Wyeth
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Defendant Wyeth Pharmaceuticals, Inc., (“Wyeth”), respectfully submits the following Memorandum of Law in support of its motion to dismiss the complaint (“Complaint”) filed by Plaintiff Joseph Dykstra (“Dykstra”) for failure to state a claim upon which relief can be granted pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure.

PRELIMINARY STATEMENT

On or about June 6, 2008, Dykstra, a former employee of Wyeth, filed a Verified Complaint in the Supreme Court of the State of New York, County of Rockland (the “Complaint”), asserting a claim against Wyeth under New York’s whistleblower statute, N.Y. Labor Law § 740.¹ On August 22, 2008, within 30 days after receiving a copy of the Complaint, Wyeth removed the action to this Court.

As demonstrated below, Dykstra’s Complaint should be dismissed as a matter of law because it fails to allege that he disclosed to his supervisor any activity that constituted a violation of a law, rule, or regulation, as required under Section 740 of the New York Labor Law. Section 740 provides a narrow and specific statutory exception to the employment-at-will doctrine and prohibits employers from retaliating against employees who disclose to their supervisors activity that constitutes an actual violation of a law, rule, or regulation, which violation creates a substantial and specific danger to the public health or safety. N.Y. LABOR LAW § 740(2)(a). Dykstra’s legal claim under Section 740 is predicated upon an alleged violation of 21 C.F.R. § 600.14, a regulation promulgated by the United States Food and Drug Administration (the “FDA”) relating to a company’s required disclosures to the FDA. However, nowhere in the Complaint does Dykstra allege that he complained to his supervisor that Wyeth

¹ A copy of Dykstra’s Complaint is attached as Exhibit 1 to the Declaration of James H. McQuade (“McQuade Decl.”) filed herewith.

had failed to disclose any event to the FDA in violation of 21 C.F.R. § 600.14. Accordingly, the allegations in the Complaint are insufficient to establish an essential element of Dykstra's claim, and the Complaint should be dismissed in its entirety for failure to state a claim upon which relief may be granted pursuant to Rule 12(b)(6) of the Rules of Federal Procedure.

ALLEGATIONS IN THE COMPLAINT²

Wyeth is a company engaged in the development and manufacture of pharmaceutical products, and, as such, it is regulated by the FDA. *See* McQuade Decl. Ex. 1, ¶¶ 9-11. The only law, rule, or regulation of the FDA referenced in the Complaint is 21 C.F.R. § 600.14. The Complaint alleges that, pursuant to 21 C.F.R. § 600.14, Wyeth "is required to report to the Center of Biologics Evaluation and Research and the Office of Compliance and Biologics Quality within 45 days of any event associated with the manufacturing, which includes testing, processing, packing, labeling, or storage, or with the holding or distribution of a licensed biological product, in which the safety, purity, or potency of a distributed product may be affected." *Id.*, ¶ 12. The Complaint further alleges that the FDA issued this regulation to prevent "substantial and specific danger to the public health or safety." *Id.*, ¶ 13.

Dykstra alleges that, while working as an aseptic setup worker at Wyeth in late February or early March 2007, he witnessed an event that constituted violations of Wyeth's internal standard operating procedures. *Id.*, ¶¶ 14-23. Dykstra alleges that he reported these violations of Wyeth's internal standard operating procedures to his supervisor, Humberto Zayas, on the same day he witnessed the alleged violations. *Id.*, ¶¶ 22, 29. The Complaint further alleges that Wyeth failed to report these alleged violations of standard operating procedures to the FDA in violation of 21 C.F.R. § 600.14 and that Wyeth's violation of 21 C.F.R. § 600.14 caused a

² This Section is derived from the factual allegations of the Complaint. Wyeth assumes, for the purpose of this motion only, that the factual allegations in the Complaint are true.

“substantial and specific danger to the public health or safety.” *Id.*, ¶¶ 25-28. Dykstra further alleges in his Complaint that, instead of reporting these alleged standard operating procedure violations to the FDA, Wyeth terminated his employment because he had reported the alleged violation of standard operating procedures to his supervisor Humberto Zayas. *Id.*, ¶¶ 29-31.

Although Dykstra’s legal claim under New York Labor Law § 740 is predicated on an alleged violation of 21 C.F.R. § 600.14, which relates to disclosures to the FDA, nowhere in the Complaint does Dykstra allege that he complained to his supervisor or anyone else at Wyeth that Wyeth had failed to disclose any event to the FDA in violation of 21 C.F.R. § 600.14.

ARGUMENT

The Complaint Should Be Dismissed Because It Fails To Allege That Dykstra Complained Of An Actual Violation Of Law, Rule, Or Regulation, As Required By New York Labor Law Section 740

New York Labor Law § 740(2) provides in pertinent part that:

2. An employer shall not take any retaliatory personnel action against an employee because such employee does any of the following:

(a) discloses or threatens to disclose to a supervisor . . . an activity, policy or practice of the employer that is in violation of law, rule or regulation which violation creates and presents a substantial and specific danger to the public health or safety . . . [or]

(c) objects to, or refuses to participate in any such activity, policy or practice in violation of a law, rule or regulation.

N.Y. LAB. LAW § 740(2). Section 740(2) consistently is interpreted as a “narrow exception to the general rule of employment at will.” *Roach v. Computer Assoc. Int’l, Inc.*, 224 A.D. 676, 677, 638 N.Y.S.2d 699, 700 (2d Dep’t 1996) (granting motion to dismiss for failure to state cause of action because plaintiff failed to allege any disclosure of actual violations of law).

A cause of action based upon § 740(2) “is available to an employee who discloses or threatens to disclose an employer activity or practice which (1) is in violation of a law, rule or

regulation, and (2) creates a substantial and specific danger to public health.” *Deshpande v. TJH Med. Serv., P.C.*, 52 A.D.3d 648, -- N.Y.S.2d --, 2008 WL 2456784, at *2 (2d Dep’t 2008) (granting motion to dismiss because “plaintiff failed to allege a violation of any law, rule or regulation with requisite particularity and specificity necessary to support a cause of action under Labor Law § 740”) (quotations omitted). Section 740 requires a plaintiff to allege an actual violation of a law, rule, or regulation. *Id.* “A good faith, reasonable belief that a violation occurred is insufficient.” *Id.* (citing cases).

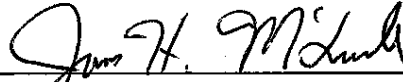
In the present case, the only specific violation of a law, rule, or regulation identified in Dykstra’s Complaint is the alleged violation of 21 C.F.R. § 600.14, which relates to disclosures of events to the FDA. Dykstra’s Complaint alleges that, in violation of 21 C.F.R. § 600.14, Wyeth failed to disclose to the FDA the alleged incident Dykstra observed involving violations of Wyeth’s internal standard operating procedures, which he claims he previously had disclosed to his supervisor. However, the Complaint does not allege that Dykstra ever complained to his supervisor or anyone else at Wyeth about Wyeth’s failure to disclose violations of its standards operating procedures to the FDA. Instead, the Complaint alleges only that Dykstra simply complained to his supervisor about violations of Wyeth’s internal standard operating procedures, which are not laws, rules or regulations for purposes of Section 740. Because Dykstra’s Complaint fails to allege that he disclosed to his supervisor an actual, violation of a specific law, rule, or regulation, his Complaint fails to state a claim upon which relief can be granted, and his Complaint should be dismissed as a matter of law.

CONCLUSION

For the foregoing reasons, Wyeth's motion to dismiss for failure to state a claim should be granted.

Dated: New York, New York
August 29, 2008

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